

Exhibit 16

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June 8, 2020

VIA E-MAIL

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Re: ***In re Novartis and Par Antitrust Litigation***, 1:18-cv-04361-AKH
Plaintiffs' Rule 45 Subpoena to Lupin Pharmaceuticals, Inc. and Lupin
Limited

Dear Counsel,

I write on behalf of Plaintiffs in the above-referenced litigation regarding the document subpoena to Lupin Pharmaceuticals, Inc. and Lupin Limited (together "Lupin") dated February 11, 2019. We are in receipt of your April 17, 2020 correspondence as well as your email dated June 2, 2020 concerning Plaintiffs' Motion to Compel (ECF No. 244).

To be clear, while we understand that Lupin currently owns Novel Laboratories, Inc. ("Novel")—having acquired its assets in 2016—Plaintiffs' Motion to Compel (ECF No. 244) concerns only Plaintiffs' February 11, 2019 subpoena to Lupin for documents regarding Lupin's generic Exforge manufactured pursuant to ANDA No. 090245. We have written separately concerning Novel's subpoena response and production.

Plaintiffs are puzzled by the surprise expressed in your June 2 email concerning our Motion. As you are aware, Plaintiffs and Lupin have exchanged numerous letters and emails dating back to the spring of 2019, wherein Plaintiffs have made Lupin aware of outstanding deficiencies in its production or planned production.¹ Lupin's last correspondence dated April 17, 2020 made clear the parties were at an impasse because Lupin claimed to have "fully complied with Plaintiffs' Subpoena" when, in fact, Plaintiffs have been telling Lupin for many months that it has not. In particular, you now assert that the categories of documents sought by Plaintiffs' Motion were not "even mentioned in Plaintiffs' April 10 letter to Lupin." But, as you are well aware,

¹ Plaintiffs have exchanged letters or e-mail with Lupin regarding this topic on nearly twenty occasions: (1) 2/25/2019; (2) 4/3/2019; (3) 4/19/2019; (4) 4/26/2019; (5) 6/14/2019; (6) 6/26/2019; (7) 7/16/2019; (8) 7/22/2019; (9) 8/5/2019; (10) 8/13/2019; (11) 9/25/2019; (12) 10/8/2019; (13) 12/4/2019; (14) 1/13/2020; (15) 2/3/2020; (16) 2/6/2020; (17) 2/28/2020; (18) 4/10/2020; and (19) 4/17/2020. Additionally, Plaintiffs' counsel have conducted telephonic meet-and-confers with Lupin's counsel on at least five occasions: (1) 2/4/2019; (2) 3/11/2019; (3) 3/29/2019; (4) 5/22/2019; and (5) 1/29/2020.

Plaintiffs also outlined these deficiencies in detail in, *inter alia*, our January 13 correspondence.² Plaintiffs also listed the unique alphanumeric identifiers of the specific process validation reports and process validation batch records Lupin must produce.³

Finally, the nine categories of documents sought by Plaintiffs' motion should come as no surprise to Lupin since Lupin *already agreed* to produce these documents in May 2019. A brief history: on April 3, 2019, in response to Lupin's offer in March to produce certain documents responsive to Plaintiffs' subpoena Request Nos. 4 and 5 that included New Product Launch Meeting Minutes, Plaintiffs identified for Lupin the additional documents that would need to be produced.⁴ Lupin responded on April 19, 2019 and, on May 22, 2019, the parties held a teleconference whereupon Lupin and Plaintiffs agreed on the scope of the production – exactly the documents sought by subpoena Request Nos. 4 and 5 as narrowed in Plaintiffs' April 3, 2019 letter and currently sought in Plaintiffs' Motion. Since that meet-and-confer, Lupin has confirmed in writing at least five different times that Lupin and Plaintiffs agreed on the scope of Lupin's document production:

- “Lupin is making this production as part of an agreement between Lupin and Plaintiffs regarding the narrowed scope of the document requests in the Subpoena.” April 26, 2019, letter to D. Chiorean;

² See Plaintiffs' January 13, 2020 Letter at 1-2 (“Lupin's production is insufficient because Plaintiffs are unable to determine, *inter alia*:

1. The extent to which Lupin considered and took steps towards launching generic Exforge earlier.
2. The sequence of activities Lupin undertook to prepare for its generic Exforge launch, including when Lupin commenced preparations for its planned March 2015 launch.
3. When Lupin ordered API intended for use in its first commercial batches of generic Exforge manufactured for launch, and in what quantities.
4. When Lupin ordered other excipients, packaging, and other items necessary for use in its first commercial batches of generic Exforge manufactured for launch, and in what quantities.
5. Lupin's generic Exforge launch timeline(s) – and whether or not they were adjusted over time.
6. Whether Lupin encountered any difficulties in manufacturing its commercial batches of generic Exforge in preparation for the March 2015 launch.
7. When Lupin purchased or made available the equipment used in the manufacturing of generic Exforge commercial batches in advance of its March 2015 launch.
8. The amount of generic Exforge finished product inventory that Lupin had on hand at the time of launch in March 2015.”)

³ *Id.* at 2.

⁴ See Plaintiffs' April 3, 2019 Letter at 2-3 (clarifying that in addition to minutes from Lupin's New Product Launch meetings, Request 4 also requires “(i) launch timelines, new product launch meeting minutes, projections, and forecasts, including any assumptions used; (ii) schedules; (iii) launch updates, action items from new product launch meetings, and launch team meeting minutes; (iv) “at-risk” launch analyses and discussions; (v) manufacturing forecasts; (vi) sourcing of active and inactive ingredients (including communications with any suppliers); (vii) exhibit batches, scale up, validation, building and maintenance of commercial quantities, and/or manufacture, sale, transfer, or destruction of same; and (viii) public statements (including statements to investors or courts) and competitive intelligence.”); *Id.* at 3-4 (reiterating Request No 5, but offering to limit its time period to “documents starting on the date Lupin filed its ANDA and ending on 5/1/2015,” accepting documents “sufficient to show” instead of “all documents,” and clarifying that “Plaintiffs seek documents only from those facilities proposed, contemplated, or actually used in the development, regulatory approval, scale-up, validation, commercial manufacturing and launch of Lupin's Generic Exforge.”).

- “Lupin is making this production as part of an agreement between Lupin and Plaintiffs regarding the narrowed scope of the document requests in the Subpoena.” June 14, 2019, letter to D. Chiorean;
- “Novel is willing to produce the *same categories of documents that Lupin agreed to produce*. . . .”⁵ July 16, 2019 e-mail to D. Chiorean (emphasis added);
- “Lupin is making this production as part of an agreement between Lupin and Plaintiffs regarding the narrowed scope of the document requests in the Subpoena.” August 5, 2019, e-mail to D. Chiorean;
- “Lupin is making this production as part of an agreement between Lupin and Plaintiffs regarding the narrowed scope of the document requests in the Lupin Subpoena.” October 8, 2019 e-mail to D. Chiorean.

Far from being “unreasonably broad,” Plaintiffs’ Motion, in enumerating the nine categories of documents sought, *further narrows* the categories of documents Lupin already agreed to produce in May 2019.⁶ Consequently, Plaintiffs have already “identif[ied] targeted categories of documents [we] seek”. If, however, you have a specific question or need further clarification about any of the nine categories of documents, we are available to discuss. Otherwise, we look forward to your production forthwith.

Very truly yours,

/s/ Dan Chiorean

Dan Chiorean

cc: Plaintiffs’ Counsel (via email)

⁵ Novel is a Lupin subsidiary that was also subject to third-party discovery. Novel and Lupin are represented by the same counsel for the purposes of this case.

⁶ Compare Plaintiffs’ April 3, 2019 Letter at 2-4 with ECF No. 245 at 2-3.